Appl. No. 09/381,497

Amdt. dated July 28, 2004

Amendment Under 37 CFR 1.116 Expedited Procedure

PATENT

## REMARKS

Status of the claims

Claims 1-4, 7-11, 13, 14, 16, 17, 22-26, and 29-32 are pending in the application. Claim 1 has been amended upon entry of the instant amendment.

The amendment to claim 1 adds no new matter. It corrects a typographical error that Applicants believe was inadvertently introduced in a previous amendment to claim 1.

Rejection under 35 U.S.C. § 103

All of the pending claims stand rejected as allegedly obvious. Applicants disagree for reasons of record. However, in order to expedite prosecution, Applicants submitted a Declaration under 37 C.F.R. § 1.132 by David J. FitzGerald. This Declaration was filed in a Supplemental Amendment mailed on March 11, 2004. Attached as Appendix A is a copy of the Supplemental Amendment and transmittal, along with a copy of the stamped post card demonstrating that it was received at the patent office on March 15, 2004. Applicants respectfully request consideration of the previously filed Rule 132 Declaration.

In the Declaration, Dr. FitzGerald provides evidence that one of skill could not reasonably predict the high level of expression, retention of parental IgG binding affinity, and superior toxicity and efficacy of RFB4ds(Fv) immunoconjugates. He indicates that RFB4 expresses surprisingly well from the perspective of one of skill in the art. He first compares its expression property to that of another anti-CD22 antibody. Next, he explains that the superior expression and binding characteristics are unpredictable, because the art cannot predict which antibody sequences will express well or be stable.

Further, Dr. FitzGerald attests to the fact that the finding that RFB4 immunotoxins retain the binding specificity and affinity of the parent RFB4 IgG is unusual. It is surprising, not only in contrast to IL2-containing immunoconjugates, but also in comparison to many recombinant immunotoxins.

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Last, he reiterates that RFB4dsFv immunotoxins have over 100 times better than any immunotoxin that could be produced using LL2 as the binding moiety, and have potent antitumor activity in animals and in human phase I trials.

In summary, Dr. FitzGerald's Declaration under 37 C.F.R. provides evidence that one of skill in the art considers the superior expression, binding, and toxicity of RFB4dsFv to be surprising and unexpected.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection.

## **CONCLUSION**

Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

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